

REMARKS

This Amendment is submitted in response to the non-final Office Action mailed on October 9, 2008. A petition for a one month extension of time are submitted herewith. The Director is authorized to charge the amount of \$130.00 for the cost of the petition for a one month extension of time, and any additional fees which may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 112701-746 on the account statement.

Claims 1-4, 8-9 and 11-26 are pending in this application. Claims 5-7 and 10 were canceled without prejudice or disclaimer, and Claims 17-21 were previously withdrawn. In the Office Action, Claims 1-4, 8-10, 11-16 and 22-26 are rejected under 35 U.S.C. §112. Claims 1-4, 8-9, 12-16 and 22-26 are rejected under 35 U.S.C. §103. In response, Claims 1, 9, 15 and 22 have been amended and Claims 24 and 26 have been canceled without prejudice or disclaimer. These amendments do not add new matter. In view of the amendments and/or for at least the reasons set forth below, Applicants respectfully submit that the rejections should be withdrawn.

In the Office Action, Claims 24 and 26 are rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description and enablement requirements. The Patent Office asserts that the Specification only discloses a composition of carotenoid-containing material and fails to sufficiently describe or enable a method of treating cardiovascular diseases or cancers. See, Office Action, page 3, lines 8-10 and 14-23; page 5, lines 16-23; page 6, lines 1-9. In response, Applicants have canceled Claims 24 and 26. Applicants respectfully submit that the cancellation of Claims 24 and 26 renders moot the Patent Office's rejection.

Accordingly, Applicants respectfully request that the rejection of Claims 24 and 26 under 35 U.S.C. §112, first paragraph, be withdrawn.

In the Office Action, Claims 1-4, 8-10, 11-16 and 22-26 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. The Patent Office asserts that the limitation "such that" in Claims 1, 15 and 22 "is indefinite because it does not mean that *cis:trans* is at 20:80. . . [but] only suggest[s] that i[t] may be. . . at 20:80." See, Office Action, page 6, lines 16-18. In response, Applicants have amended Claims 1, 9, 15 and 22 to recite, in part, a carotenoid-containing material, enriched in *cis*-isomer of the carotenoid compound, "wherein the *cis:trans* isomer ratio of the carotenoid compound is at least 20:80." This amendment does not

add new matter. The amendment is supported in the Specification, for example, at page 6, lines 26-30; page 7, lines 1-3; page 11, lines 28-29; page 12, lines 3, 9-10 and 16. Applicants respectfully submit that currently amended Claims 1, 9, 15 and 22 clearly indicate that the *cis:trans* isomer ratio of the carotenoid compound must be at least 20:80. Thus, Applicants respectfully submit that Claims 1, 9, 15 and 22 are not indefinite.

Accordingly, Applicants respectfully request that the rejection of Claims 1-4, 8-10, 11-16 and 22-26 under 35 U.S.C. §112, second paragraph, be withdrawn.

In the Office Action, Claims 1-4, 8-9, 12-16 and 22-26 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,965,183 to Hartal et al. ("*Hartal*") in view of Journal of Food Science, Vol. 52, No. 3, pp. 669-72 (1987) by Chandler et al. ("*Chandler*"). For at least the reasons set forth below, Applicants respectfully submit that, even if combinable, the cited references fail to disclose or suggest each and every element of independent Claims 1, 9, 15 and 22 and Claims 2-4, 8, 12-14, 16, 22-23 and 25 that depend therefrom. Furthermore, Applicants respectfully submit that one of ordinary skill in the art would have no reason to combine the cited references.

Currently amended independent Claims 1, 9 and 15 recite, in part, a composition comprising at least one carotenoid-containing material, enriched in *cis*-isomer of the carotenoid compound, wherein the *cis:trans* isomer ratio of the carotenoid compound is at least 20:80, and wherein the carotenoid compound is selected from the group consisting of lycopene, xeaxanthine, beta-cryptoxanthin, capsanthine, canthaxanthine, phytofluene, phytoene, and combinations thereof. Similarly, independent Claim 22 recites, in part, a method for improving skin health comprising the step of administering to a patient in need of improved skin health at least one carotenoid-containing material, enriched in *cis*-isomer of the carotenoid compound, wherein the *cis:trans* isomer ratio of the carotenoid compound is at least 20:80, and wherein the carotenoid compound is selected from the group consisting of lycopene, xeaxanthine, beta-cryptoxanthin, capsanthine, canthaxanthine, phytofluene, phytoene, and combinations thereof. These amendments do not add new matter. The amendments are supported in the Specification at, for example, page 6, lines 26-30; page 7, lines 1-3; page 11, lines 28-29; page 12, lines 3, 9-10 and 16.

Carotenoids are natural products that have beneficial effects such as alleviating chronic diseases. See, Specification, page 1, lines 12-13. Isolated or enriched carotenoid compounds

extracted from a natural source such as a plant or an animal are already known in the art. See, Specification, page 1, lines 11-16. However, the carotenoids in these naturally-occurring compounds are insufficiently bioavailable and, thus, their full beneficial effects cannot be realized. See, Specification, page 1, lines 15-17. In contrast, the present claims provide a carotenoid compound with improved bioavailability. See, Specification, page 2, lines 1-4. The *cis*-isomer content of naturally-occurring carotenoid compounds that are extracted from plants or animals is low. See, Specification, page 5, lines 20-22. For this reason, after the naturally-occurring carotenoid compounds are extracted from the plant or animal, they are subjected to further treatment such as microwave irradiation or solubilisation followed by phase separation in order to modify the isomer profile of the carotenoid. See, Specification, page 6, lines 4-9, 14-17 and 26-30. By subjecting the naturally-occurring carotenoid compound to additional treatment to increase its *cis*-isomer content such that the *cis:trans* isomer ratio is at least 20:80, the bioavailability and/or bioefficacy of the carotenoid compound is increased. See, Specification, page 6, lines 4-9; page 7, lines 1-7. In contrast, Applicants respectfully submit that the cited references fail to disclose each and every element of the present claims.

For example, the cited references fail to disclose or suggest a carotenoid-containing material wherein the *cis:trans* isomer ratio of the carotenoid compound is at least 20:80, and wherein the carotenoid compound is selected from the group consisting of lycopene, xeaxanthine, beta-cryptoxanthin, capsanthine, canthaxanthine, phytofluene, phytoene, and combinations thereof as required, in part, by currently amended independent Claims 1, 9, 15 and 22. *Hartal* is entirely directed to providing stable lycopene compositions with a high staining power for use in food coloring. See, *Hartal*, column 2, lines 17-40. Nowhere does *Hartal* disclose or suggest enriching the *cis*-isomer content of the lycopene to increase its bioavailability. In fact, the Patent Office admits that *Hartal* fails to disclose a *cis:trans* isomer ratio of at least 20:80 for the claimed carotenoid compounds. See, Office Action, page 7, lines 23-24. Instead, the Patent Office relies on *Chandler* for the claimed element.

However, *Chandler* also fails to disclose a carotenoid compound selected from the group consisting of lycopene, xeaxanthine, beta-cryptoxanthin, capsanthine, canthaxanthine, phytofluene, phytoene, and combinations thereof, wherein the *cis:trans* isomer ratio of the carotenoid compound is at least 20:80. The Patent Office asserts that *Chandler* discloses *cis:trans* isomer ratios in the claimed range. See, Office Action, page 8, lines 1-6. However,

Chandler is entirely directed to the separation and identification of cis- and trans- isomers of alpha- and beta-carotene. See, *Chandler*, Title (“HPLC Separation of Cis-Trans Carotene Isomers in Fresh and Processed Fruits and Vegetables”); Introduction, page 669, paragraphs 3-5. Furthermore, the tables relied on by the Patent Office merely show the percentage of cis- and trans-isomers of beta-carotene. See, *Chandler*, Tables 1-2. Nowhere does *Chandler* disclose or suggest selected from the group consisting of lycopene, xeaxanthine, beta-cryptoxanthin, capsanthine, canthaxanthine, phytofluene, phytoene, and combinations thereof in which the *cis:trans* isomer ratio is at least 20:80.

The Patent Office nevertheless asserts that merely because lycopene is a type of carotenoid, one of ordinary skill in the art would reasonably expect that lycopene could be used as the type of carotenoid taught by *Chandler*. See, Office Action, page 8, lines 13-21. However, *Chandler* specifically states that the column used in its experiments “is highly selective toward carotene isomers and under the solvent conditions employed other carotene[oids] such as lycopene do not elute.” See, *Chandler*, page 671, paragraph 2, lines 13-15. As such, one of ordinary skill in the art would not consider lycopene an obvious modification of carotene and would have no reason to use lycopene in the column of *Chandler* to analyze cis-trans isomer content.

Moreover, one of ordinary skill in the art understands that lycopene is distinct from carotene because cis-isomers of carotenoids only exist naturally for beta-carotene, not for lycopene. For example, *Chandler* discloses that certain fresh fruits such as plums and nectarines have a cis-isomer content of beta-carotene greater than 20%. See, *Chandler*, Table 2. In contrast, the cis-isomer content of lycopene for a tomato oleoresin is merely 7%. See, Specification, page 5, lines 20-22. In order to increase the cis-isomer content of lycopene to greater than 20%, the oleoresin must be subjected to further treatment such as microwave irradiation or solubilisation followed by phase separation. See, Specification, page 6, lines 14-16 and 26-30. Therefore, the cis-isomer content of carotene disclosed in *Chandler* is not necessarily the same for lycopene or any other carotenoid and, contrary to the Patent Office’s assertion, cannot be relied on for the disclosure of a *cis:trans* isomer ratio of 20:80 in the claimed carotenoid compounds. Furthermore, *Chandler* fails to disclose or suggest carotenoid compounds containing lycopene, xeaxanthine, beta-cryptoxanthin, capsanthine, canthaxanthine, phytofluene, phytoene, or combinations thereof. As such, *Chandler* fails to disclose a

carotenoid-containing material wherein the *cis:trans* isomer ratio of the carotenoid compound is at least 20:80, and wherein the carotenoid compound is selected from the group consisting of lycopene, zeaxanthine, beta-cryptoxanthin, capsanthine, canthaxanthine, phytofluene, phytoene, and combinations thereof as required, in part, by the present claims.

Furthermore, one of ordinary skill in the art would have no reason to combine the cited references because *Chandler* teaches away from the present claims. In this regard, references must be considered as a whole and those portions teaching against or away from each other and/or the claimed invention must be considered. *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve Inc.*, 796 F.2d 443 (Fed. Cir. 1986). “A prior art reference may be considered to teach away when a person of ordinary skill, upon reading the reference would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the Applicant.” *Monarch Knitting Machinery Corp. v. Fukuhara Industrial Trading Co., Ltd.*, 139 F.3d 1009 (Fed. Cir. 1998), quoting, *In re Gurley*, 27 F.3d 551 (Fed. Cir. 1994).

Chandler is entirely directed to determining the amount of *cis*- and *trans*- isomers of beta-carotene in certain food products to assess the vitamin A activity of the food products. See, *Chandler*, page 669, Introduction, paragraphs 2-3 and 5. *Chandler* specifically teaches that “[i]somerization reactions of the all *trans* form to *cis* isomers reduces the bioavailability of the carotenoids as vitamin A precursors.” See, *Chandler*, page 669, paragraph 2, lines 4-6. *Chandler* further notes that the conversion of *trans* beta-carotene isomers to *cis*-isomers results in a 15 – 35 % loss of vitamin A value. See, *Chandler*, page 669, paragraph 3, lines 2-5. Therefore, *Chandler* teaches away from increasing the *cis:trans* isomer content of a carotenoid to increase its bioavailability.

In contrast, the present claims are entirely directed to a compound enriched in *cis*-isomer of the carotenoid compound. See, Specification, Abstract; page 1, lines 3-5. In order to obtain a carotenoid compound with an increased *cis*-isomer content, a naturally occurring extract, concentrate or oleoresin of carotenoid is subjected to further treatment intended to modify its isomer profile. See, Specification, page 6, lines 14-16 and 26-30. By increasing the *cis:trans* isomer ratio up to at least 20:80, the present claims provide a carotenoid compound with a higher bioavailability than the compound alone. See, Specification, page 7, lines 1-7. This is in direct contrast to *Chandler*’s teaching that a higher *cis*-isomer content reduces the bioavailability of the

carotenoid. Therefore, *Chandler* teaches away from compounds enriched in *cis*-isomer of the carotenoid compound in accordance with the present claims.

Accordingly, Applicants respectfully request that the rejection of Claims 1-4, 8-9, 12-16 and 22-26 under 35 U.S.C. §103(a) to *Hartal* and *Chandler* be withdrawn.

Applicants note that the Patent Office did not reject Claim 11 that depends from Claim 9. Applicants respectfully submit that Claim 11 is patentable over the *Hartal* and *Chandler* for at least the reasons discussed previously.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same. In the event there remains any impediment to allowance of the claims that could be clarified in a telephonic interview, the Examiner is respectfully requested to initiate such an interview with the undersigned.

Respectfully submitted,

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